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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/497,967	02/04/2000	Theodore G. Clark	235.00170101	8124

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EXAMINER

FIELDS, IESHA P

ART UNIT PAPER NUMBER

1645

DATE MAILED: 01/02/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/497,967

Applicant(s)

CLARK ET AL.

Examiner

Ilesha P Fields

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-40 is/are pending in the application.
- 4a) Of the above claim(s) 12,13,22 and 24-40 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-11,14-21 and 23 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 04 February 2000 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Applicant's election with traverse of Group I, claims 1-11, 14-21 and claim 23 (Paper Number 10) received on August 6, 2001 is acknowledged. In addition, applicants have elected SEQ ID NO:7 and a 55 kDa I-antigen for examination. The traversal is on the grounds that the Commissioner has partially waived the requirement of 37 C.F.R. 1.141. et seq. and permits a reasonable number of sequences to be claimed in a single application. Applicants have further traversed the restriction stating that according to MPEP 803, if the search and examination of an entire application can be made without serious burden, the Examiner must examine it on the merits, even though it includes claims to distinct or independent inventions. The argument that the restriction is improper because the application can be searched without serious burden is not found persuasive. It is the Examiner's position that it would be an undue burden to search each of the inventions as indicated by the divergent subject matter and different classification. For instance a search of the prior art to Group I would not reveal prior art of Groups II-VI as indicated by their different classification. Further with regards to the traversal on the ground that it would not be a serious burden to search each of the claimed inventions, it is the Examiner's position that a search of the inventions is not co-extensive particularly with regard to the literature search. A reference which would anticipate the invention of one group would not necessarily anticipate or make obvious any of the other groups. Consequently, claims 1-40 are pending and claims

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1-11, 14-21 and 23 (Group I) only to the extent of SEQ ID NO: 7 and a 55 kDa i-antigen are under examination. The claims that read Applicants elected invention are claims 3-4, 6-10, 14, 16-21 and 23.

The requirement is still deemed proper and is therefore made **FINAL**.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

1. Claims 3-4, 6-10, 16, and 18 are rejected under 35 U.S.C. 102(b) as being anticipated by Clark et al.

The claims are drawn to a nucleic acid sequence comprising a polynucleotide fragment having a nucleotide sequence that encodes an i-antigen polypeptide.

Clark et al (PNAS 1992 Vol. 89 pp 6363-6367) disclose a nucleic acid sequence comprising a polynucleotide fragment having a nucleotide sequence that encodes an i-antigen polypeptide. The nucleic acid sequence of Clark et al. is being viewed as a polynucleotide fragment.

Claim Rejections - 35 USC § 112

2. Claims 3-4, 6-10, 16, and 18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A) The claims are vague and indefinite in recitation of a "polynucleotide fragment". One skilled in the art would be unable to determine the meets and bounds of such a limitation. For example, what is the length of the fragment? Without a clear definition as to what constitutes as a fragment, one of skill in the art would be unable to replicate the claims.

B) The claims are further vague and indefinite in recitation of "at least an antigenic portion" for the same reasons stated above. For example, what does at least an antigenic portion of an i-antigen encompass? Without a clear definition as to what at least an antigenic portion of an i-antigen encompasses one of skill in the art would be unable to replicate the claims.

C) The claims are further vague and indefinite in recitation of an "organism". Claim 6 recites a nucleic acid molecules that is capable of expressing the polypeptide encoded by the nucleic acid sequence in a cell or organism, wherein the cell or organism is selected from the group consisting of a bacterium, a protozoan, a yeast, an insect and an animal or organism. The Examiner is unclear as to what the Applicant is claiming in addition to the organisms recited in the claim. Clarification is requested.

D) The claims are further vague and indefinite in recitation of an antigenic polypeptide that shares a "significant level". One skilled in the art would be unable to

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determine the meets and bounds of such a limitation. For example, what constitutes as a significant level? Without a clear definition as to what constitutes a "significant level" one of skill in the art would be unable to replicate the claims.

E) The claims are further vague and indefinite in recitation of "substantially complementary". One skilled in the art would be unable to determine the meets and bounds of such a limitation. For example, what does substantially complementary encompass? Without a clear definition as to what constitutes as "substantially complementary" one of skill in the art would be unable to replicate the claims.

F) The claims are further vague and indefinite in recitation of a "plurality of molecules". One skilled in the art would be unable to determine the meets and bounds of such a limitation. For example, how many molecules or which molecules of the pathway is the applicant claiming? Without a clear definition as to what a plurality of molecules encompasses, one of skill in the art would be unable to replicate the claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Iesha P Fields whose telephone number is (703) 605-1208. The examiner can normally be reached on 7am-3:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on (703) 308-3909. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3014 for regular communications and (703) 308-4242 for After Final communications.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Ilesha Fields

December 31, 2001



MARK NAVARRO
PRIMARY EXAMINER